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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,881	10/05/2005	Sander Jan Hendrik Van Deventer	28902.nob11	6763

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EXAMINER	
TON, THAIAN N	

ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
12/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,881	VAN DEVENTER ET AL.	
	Examiner	Art Unit	
	Thaian N. Ton	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,20,21 and 23* is/are pending in the application.

4a) Of the above claim(s) *10-17 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' Amendment and Response, 2/24/09, has been entered. Claims 1-17, 20, 21 and 23 are pending; claims 10-17 and 23 are withdrawn; claims are under current examination.

This rejection is non-final.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9, 20, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mavilio *et al.* (Blood, 83(7): 1988-1997, April 1, 1994, IDS) when taken with Setoguchi *et al.* (J. of Immunology, 165(10): 5980-5986, 2000, IDS).

Mavilio teach the collection of peripheral blood mononuclear cells (PBMCs), culturing of the cells for 72 hours with PHA and IL-2 stimulation. Mavilio teach that viral infection with a LNSN vector containing LNGFR cDNA, was performed by exposure of the stimulated peripheral blood lymphocytes (PBLs) to a cell-free viral stock in the presence of polybrene. Forty-eight hours after infection, PBLs were selected in RPMI 1640 media supplemented with human serum, human recombinant IL-2, and G418. Mavilio teach that to improve retroviral infection, human PBLs were co-cultivated with virus producing cells for 48-72 hours. The cells were analyzed by flow cytometry for LNGFR expression. See p. 1989, col. 1-2, Infection of human PBLs. Thus, Mavilio teach modifying at least a portion of mammalian peripheral blood mononuclear cells, among which cells lymphocytes are not selected or enriched on the basis of antigen specificity (IL-2 stimulation is non-

antigen specific), introducing an expression construct into the cells, and recovering the modified cells by flow cytometry. Regarding claim 2, Mavilio fulfill this limitation because they use IL-2 to stimulate PBLs, and would thus provide an enriched PBL cell population. Regarding claim 3, Mavilio teach lymphocytes. Regarding claim 4, Mavilio teach culturing the cells for 72 hours prior to viral infection. Regarding claim 5, Mavilio teach using PHA and IL-2, which are proliferating agents. Regarding claim 6, Mavilio teach culturing the cells with phytohemagglutinin (PHA). Regarding claim 7, Mavilio teach using flow cytometry to isolate retroviral transduced cells. Regarding claim 8, Mavilio teach lymphocytes. Regarding claims 20-21, Mavilio teach the production of an enriched lymphocyte population, which includes B lymphocytes, T lymphocytes or CD4+ lymphocytes. Claims 20-21 do not specify that the enriched lymphocyte population includes any specific population of these cells, and their methods would inherently arrive at an enriched population of any combination of these lymphocytes, because they arrive at an enriched population of lymphocytes.

Mavilio do not specifically teach utilizing an expression construct that comprises a nucleotide sequence that encodes an IL-10 polypeptide. However, prior to the time of the claimed invention, Setoguchi teach the transfection of splenocytes with a retroviral vector encoding IL-10 (see p. 5981, *Production of replication-defective retrovirus* and *Infection of the retrovirus*).

Accordingly, it would have been obvious to the skilled artisan to modify the teachings of Mavilio to utilize an expression construct that encodes an IL-10 polypeptide, with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to make this modification in view of Setoguchi's teachings who state teach using T cells as vehicles for delivering useful agents (p. 5980, col. 2, 1st full paragraph) and further, that Il-10 is known to mediate immunosuppressive effects predominantly through down-regulation of macrophage functions and inhibition of proinflammatory cytokines produced by Th1 cells, that

IL-10 was shown to prevent disease expression and development in collagen-induced arthritis by i.p. injection of mouse IL-10, or an adenovirus murine IL-10 (p. 5980-1, bridging paragraph). Thus, Setoguchi establish the importance and efficacy of IL-10 in treatment of inflammatory disease, including arthritis, and additionally suggest the usefulness of using T cells in order to deliver therapeutic agents.

Thus, the claimed invention, as a whole, is clearly *prima facie* obvious in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thaian N. Ton whose telephone number is (571)272-0736. The examiner can normally be reached on 9-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thaian N. Ton/
Primary Examiner, Art Unit 1632